UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,978	04/21/1998	ROBERT J. OBREMSKI	45D-1750(641	5283

46267 7590 09/19/2005

HOGAN & HARTSON LLP
500 S GRAND AVE
SUITE 1900
LOS ANGELES, CA 90071

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/063,978	OBREMSKI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-25,31,35,36,39 and 40* is/are allowed.

6)☒ Claim(s) *1-22, 26-30, 32-34, 37, 38, 41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed July 5, 2005 has been entered. Claims 23 and 35 have been amended. Claims 1-42 are under consideration in the office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 23-25, 31, 35-36 and 39-40 under 35 U.S.C. 112, second paragraph; and

b) The rejection of claims 23-25, 35-36 and 39-40 under 35 U.S.C. 102(b) as being anticipated by Ekins (EP 304, 202).

Response to Arguments

3. Applicant's arguments filed July 5, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The enablement rejection of claims 1-22, 26-30, 32-34, 37-38 and 41-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is

maintained for reasons of record. The rejection was on the grounds that claims drawn to a binding assay for sensing analyte mass in a liquid sample comprising a immobilization step; wherein the immobilized substrate comprises a plurality of microscopic sorbent zones wherein a zone comprises a multi-layer matrix of an analyte binding partner; a contact step; a tagging step; an illumination step; and detection step whereby the detection of fluorescence emissions from any microscopic sorbent zone having an analyte capture complex tagged with a fluorescent label, thereby determines the analyte mass harvested from the defined volumes of sample are not enabled.

Applicants' state that the specification provides ample information that analyte mass can be determined using the claimed method. Applicants state that in their examples a dose response curve was established by plotting the fluorescence readings versus the number of DBCY5-biotin molecules and that such dose response curves can be used to determine DBCY5 masses in test samples. However all questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. See M.P.E.P 2164.08 [R-2] entitled *Enablement Commensurate in Scope With the Claims*. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought

by the claims. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003); *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971).

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984). In this case, applicants are contending that the claims be interpreted in light of the specification, since applicants arguments are drawn to using dose response curve to determine mass. However everything in the specification is not read into the claims. The claims are given their broadest possible interpretation and the claims state that detecting fluorescence thereby determines the analyte mass. Thus, the scope of the claims is not commensurate with the teachings of the specification and the claims are not enabled. The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. Limitations and examples in the specification, especially teaching about requiring a dose curve to determine analyte mass, will not generally limit what is covered by the claims. The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). In the Amgen case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

> Amgen has not enabled preparation of DNA sequences sufficient to support its all- encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them. 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Applicants' claims have not enabled a binding assay comprising the detection of fluorescence emissions to thereby determine analyte mass in a manner sufficient to support its all- encompassing claims. Despite applicants extensive statements in the specification concerning the use of dose response curves, assay conditions and non-covalent immobilization, there is little enabling disclosure of other ways to determine analyte mass. The claims fail to recite the necessary equilibrium conditions and ambient conditions to perform the method which determines analyte mass thereby failing to enabled the scope of the claims. Details for determining analyte mass are restricted to only using dose response curves. There are an infinite number of combinations of possible capture reagents, affinity constants, fluorescence image intensities, binding site saturation points, liquid bulk calculations, and molecules and their associated chemical equilibriums for one of skill in the art to determine as necessary to determine the mass of the analyte however, the limitations in the specification are not interpreted as limitations in the claims. The claims fail to recite the necessary equilibrium conditions and ambient conditions to perform the method which determines analyte

mass. There are an infinite number of combinations of possible capture reagents, affinity constants, fluorescence image intensities, binding site saturation points, liquid bulk calculations, and molecules and their associated chemical equilibriums for one of skill in the art to determine as necessary to determine the mass of the analyte however, the specification fails to supply this essential information. This disclosure is inadequate support for applicants desire to claim all other way, beside using a dose response curve to determine analyte mass. There may be many other undiscovered ways to determine analyte mass from the detection of fluorescence, however Applicant has told how to make and use only one of them and is therefore not entitled to claim all those detection and determine means. Therefore given lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 U.S.C. 112, first paragraph for lack of enablement is maintained.

Conclusion

5. Claims 23-25, 31, 35-36 and 39-40 are allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 14, 2005

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600